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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,375	07/29/2003	David S. Garvey	102258.158US2	5160
25270	7590	02/07/2006	EXAMINER	
EDWARD D GRIEFF HALE & DORR LLP 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			SAEED, KAMAL A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,375

Applicant(s)

DAVID GARVEY

Examiner

Kamal A. Saeed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 3-13, 17-27, 40-54 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-2, 16, 28-39 and 55-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

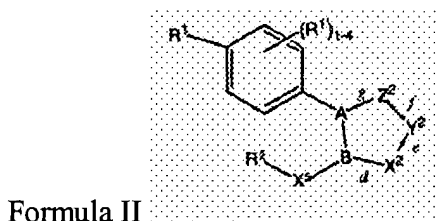
- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/19/03 and 6/21/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

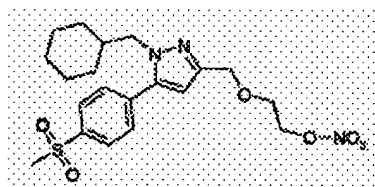
Claims 1-58, are pending in this application. Claims 3-13, 17-27, 40-54 and 58 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Response to Restriction

Applicant's election with traverse the invention of Group I, claims 1, 2, 16, 28-39 and 55-57 drawn to products of Formula I, in part drawn to compounds and compositions of



and the specific compound,



in

response filed on 07 November 2005 is acknowledged.

The examiner appreciates the proposed restriction requirement made by the Applicant. Since the method of use and the claims directed to Kit will be rejoined along with the allowable group commensurate in scope therewith, the restriction groups will remain as set forth in the previous office action.

Applicants argue that the restriction requirement does not establish that searching all the inventions would constitute an undue burden to the Patent Office. Applicant traverses the restriction requirement in that the inventions are so closely related that they do not constitute

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independent and distinct inventions. This is not found to be partially persuasive. Even though an art rejection has not been made in this application, the requirement for restriction is maintained and the search has not been extended. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) the claimed subject matter accordingly. For example, the claims encompass heteroaryl groups which are variously classified, therefore "heteroaryl" has been restricted out of the generic embodiment identified for examination. The following is an illustration of the varied classification of the heteroaryl groups: pyrazinyl is classified in class 544 and subclass 336+; pyrimidinyl is classified in class 544 and subclass 242+; pyridinyl is classified in class 546 and subclass 268.1+; oxazolyl is classified in class 548 and subclass 215+; thiazolyl is classified in class 548 and subclass 146+; etc. . . . Thus, the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. No where to Applicants argue to the contrary. No where do Applicants point out and give reasons why the claims do not involve independent or distinct subject matter. Accordingly, the restriction is proper. Moreover, it would constitute a burden to extend the search because separate search considerations would be involved in both the U.S. Patents and in the literature. The examination process following the search could easily result in different and thus burdensome considerations.

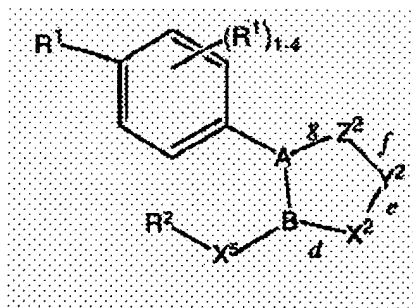
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The restriction requirement here is predicated on the premise that the various compounds involved differ in structure and element so much so as to be patentably distinct, i.e. a reference which anticipated the elected compounds claimed would not even render obvious the others. Again, 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application to a single invention. Applicant has not presented evidence that the examined subject matter is patentably indistinct from the non-examined subject matter. Nor have the even argued to the contrary. Moreover, the sheer number of variables, their huge possibilities, and the almost incomprehensible number of permutations and combinations thereof result in compounds so numerous and diverse so as to be a burden just to classify, search, and examine. Accordingly, the requirement to restrict is considered proper and is maintained. The search and examination of the application is directed to the generic embodiment identified for examination only.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the non-elected subject matter.

Scope of the elected and examined subject matter



Compound of formula II,

depicted in claim 1, wherein:

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 R^1 is:

- (a) $-S(O)_2-CH_3$;
- (b) $-S(O)_2-NR^3(D^1)$;
- (c) $-S(O)_2-N(D^1)-C(O)-CF_3$;
- (d) $-S(O)-(NH)-NH(D^1)$;
- (e) $-S(O)-(NH)-N(D^1)-C(O)-CF_3$;

 B and X^2 represent N; A , Z and Y^2 represent C; R^2 is:

- (a) lower alkyl;
- (b) cycloalkyl;
- (c) mono-, di- or tri-substituted phenyl or naphthyl, wherein the substituents are each independently:

- (1) hydrogen;
- (2) halo;
- (3) alkoxy;
- (4) alkylthio;
- (5) CN;
- (6) haloalkyl, preferably CF_3 ;
- (7) lower alkyl;
- (8) N_3 ;
- (9) $-CO_2D^1$;
- (10) $-CO_2$ -lower alkyl;
- (11) $-(C(R^5)(R^6))_n-OD^1$;
- (12) $-(C(R^5)(R^6))_n-O$ -lower alkyl;
- (13) lower alkyl- CO_2-R^5 ;
- (14) $-OD^1$;
- (15) haloalkoxy;
- (16) amino;
- (17) nitro;
- (18) alkylsulfinyl; or

 R^1 at each occurrence is independently:

- (a) hydrogen;
- (b) halogen;
- (c) methyl; or
- (d) CH_2OH ;

and

wherein R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , X^2 , A^1 , R^{31} , R^{32} , a and bb are as defined

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As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-35 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as triazine, homopiperazinyl, thiomorpholinyl, propylaminyl etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 63(+) (thiomorpholine), class 540 subclass 450(+) (homopiperziny), class 544 subclass 180(+) (triazines), 548 subclass 400(+) pyrrolidines etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Objections

Claims 1, 2, 16, 28-39 and 55-57 are objected to for containing non-elected subject matter. Claims drawn solely to the elected invention as identified supra, would appear allowable. The claims must be amended to exclude non-elected subject matter.

Telephone Inquiry

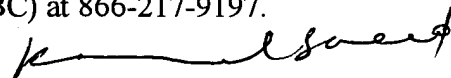
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

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Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER